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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 18, 2015**

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**OPKO Health, Inc.**  
(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-33528**  
(Commission  
File Number)

**75-2402409**  
(IRS Employer  
Identification No.)

**4400 Biscayne Blvd**  
**Miami, Florida 33137**  
(Address of Principal Executive Offices) (Zip Code)

**Registrant's telephone number, including area code: (305) 575-4100**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☒ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**ITEM 5.07. Submission of Matters to a Vote of Security Holders.****ITEM 8.01 Other Events.**

On June 18, 2015, OPKO Health, Inc. (the “Company”) held its 2015 Annual Meeting of Stockholders (the “Annual Meeting”). Below is a summary of the proposal and corresponding vote.

1. All ten nominees were elected to the Board of Directors with each director receiving votes as follows:

| Election of Directors           | For         | Withheld   |
|---------------------------------|-------------|------------|
| Phillip Frost, M.D.             | 280,567,245 | 20,412,282 |
| Jane H. Hsiao, Ph.D.            | 272,686,765 | 28,292,762 |
| Steven D. Rubin                 | 272,299,987 | 28,679,540 |
| Robert A. Baron                 | 298,914,343 | 2,065,184  |
| Thomas E. Beier                 | 292,111,995 | 8,867,532  |
| Dmitry Kolosov                  | 299,367,867 | 1,611,660  |
| Richard A. Lerner, M.D          | 299,273,701 | 1,705,826  |
| John A. Paganelli               | 292,228,594 | 8,750,933  |
| Richard C. Pfenniger, Jr.       | 298,892,008 | 2,087,519  |
| Alice Lin-Tsing Yu, M.D., Ph.D. | 266,896,935 | 34,082,592 |

There were no broker non-votes for the proposal. No other matters were considered or voted upon at the Annual Meeting.

**ITEM 7.01. Regulation FD Disclosure.**

On June 18, 2015, the Company held its Annual Meeting of Stockholders. Copies of the presentations presented at the Annual Meeting are furnished with this Current Report on Form 8-K as Exhibits 99.1, 99.2, and 99.3, respectively.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibits 99.1, 99.2, and 99.3 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Act, unless expressly stated otherwise.

**Important Information For Investors And Shareholders**

This communication does not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities or a solicitation of any vote or approval. This communication relates to a proposed business combination between Bio-Reference Laboratories, Inc. (“Bio-Reference Laboratories”) and OPKO Health, Inc. (“OPKO”). In connection with this proposed business combination, Bio-Reference Laboratories and/or OPKO will file relevant materials with the Securities Exchange Commission (the “SEC”), including an OPKO registration statement on Form S-4 that will include a proxy statement of Bio-Reference Laboratories and constitute a prospectus of OPKO. INVESTORS AND SECURITY HOLDERS OF BIO-REFERENCE LABORATORIES AND OPKO ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS AND OTHER DOCUMENTS THAT MAY BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Any definitive proxy statement (if and when available) will be mailed to shareholders of Bio-Reference Laboratories. Investors and security holders will be able to obtain free copies of these documents (if and when available) and other documents filed with the SEC by Bio-Reference Laboratories and/or OPKO through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). Copies of the documents filed with the SEC by Bio-Reference Laboratories will be available free of charge on Bio-Reference Laboratories’ website at <http://www.bioreference.com> or by contacting Bio-Reference Laboratories’ Investor Relations Department by email at [tmackay@bioreference.com](mailto:tmackay@bioreference.com) or by phone at (201) 791-2600. Copies of the documents filed with the SEC by OPKO will be available free of charge on OPKO’s website at [www.opko.com](http://www.opko.com) or by contacting OPKO’s Investor Relations Department by email at [contact@opko.com](mailto:contact@opko.com) or by phone at (305) 575-4100.

## **Participants in Solicitation**

Bio-Reference Laboratories, OPKO, their respective directors and certain of their respective executive officers may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information about the directors and executive officers of Bio-Reference Laboratories is set forth in its Annual Report on Form 10-K for the year ended October 31, 2014, which was filed with the SEC on January 13, 2015, its Quarterly Report on Form 10-Q for the quarter ended April 30, 2015 which was filed with the SEC on June 9, 2015 and its Current Reports on Form 8-K, which were filed with the SEC on March 5, 2015, April 29, 2015 and June 4, 2015. Information about the directors and executive officers of OPKO is set forth in its amended Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on February 27, 2015 and April 30, 2015, its proxy statement for its 2015 annual meeting of stockholders, which was filed with the SEC on May 7, 2015, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 which was filed with the SEC on May 11, 2015, its Current Report on Form 8-K, which was filed with the SEC on March 19, 2015 and its Quarterly Report on Form 10-K, which was filed with the SEC on June 18, 2015.

These documents can be obtained free of charge from the sources indicated above. Additional information regarding the participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement/prospectus and other relevant materials to be filed with the SEC when they become available.

## **Cautionary Statement Regarding Forward-Looking Statements**

Certain statements in this communication regarding the proposed acquisition of Bio-Reference Laboratories by OPKO, including any statements regarding the expected timetable for completing the proposed transaction, synergies, benefits and opportunities of the proposed transaction, future opportunities for the combined company and products, future financial performance and any other statements regarding OPKO's and Bio-Reference Laboratories' future expectations, beliefs, plans, objectives, financial conditions, assumptions or future events or performance that are not historical facts are "forward-looking" statements made within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipate," "believe," "ensure," "expect," "if," "intend," "estimate," "probable," "project," "forecasts," "predict," "outlook," "aim," "will," "could," "should," "would," "potential," "may," "might," "anticipate," "likely" "plan," "positioned," "strategy," and similar expressions, and the negative thereof, are intended to identify forward-looking statements.

All forward-looking information are subject to numerous risks and uncertainties, many of which are beyond the control of Bio-Reference Laboratories and OPKO, that could cause actual results to differ materially from the results expressed or implied by the statements. These risks and uncertainties include, but are not limited to: failure to obtain the required vote of Bio-Reference Laboratories' shareholders; the timing to consummate the proposed transaction; the risk that a condition to closing of the proposed transaction may not be satisfied or that the closing of the proposed transaction might otherwise not occur; the risk that a regulatory approval that may be required for the proposed transaction is not obtained or is obtained subject to conditions that are not anticipated; the diversion of management time on transaction-related issues; ability to successfully integrate the businesses; risk that the transaction and its announcement could have an adverse effect on Bio-Reference Laboratories' ability to retain customers and retain and hire key personnel; the risk that any potential synergies from the transaction may not be fully realized or may take longer to realize than expected; new information arising out of clinical trial results; and the risk that the safety and/or efficacy results of existing clinical trials will not support continued clinical development, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this communication may become outdated over time. OPKO and Bio-Reference Laboratories do not assume any responsibility for updating any forward-looking statements. Additional information concerning these and other factors can be found in Bio-Reference Laboratories' and OPKO's respective filings with the SEC and available through the SEC's Electronic Data Gathering and Analysis Retrieval system at [www.sec.gov](http://www.sec.gov), including Bio-Reference Laboratories' and OPKO's most recent Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The foregoing list of important factors is not exclusive. Bio-Reference Laboratories and OPKO assume no obligation to update or revise any forward-looking statements as a result of new information, future events or otherwise, except as may be required by law. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof.

**ITEM 9.01. Financial Statements and Exhibits.**

*(d) Exhibits*

| <u>Exhibit<br/>Number</u> | <u>Description</u>  |
|---------------------------|---|
| 99.1                      | Renal Division Presentation – 2015 Annual Meeting of Stockholders held June 18, 2015.       |
| 99.2                      | Diagnostics Division Presentation – 2015 Annual Meeting of Stockholders held June 18, 2015. |
| 99.3                      | EirGen Presentation – 2015 Annual Meeting of Stockholders held June 18, 2015.               |

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OPKO Health, Inc.

Date: June 18, 2015

By /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President,  
Chief Financial Officer

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## EXHIBIT INDEX

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*Update on*  
**Rayaldee Capsules**

June 18, 2015

## Cautionary Statement

This presentation contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," "potential" and other words of similar meaning, including statements regarding our estimated revenues and financial projections, our ability to achieve high levels of growth, the potential for our products under development, the potential of the 4Kscore™ to reduce prostate biopsies and predict the risk of aggressive prostate cancer, our ability to develop, test and launch new products, the expected timing of the clinical studies and regulatory submissions relating to our products under development, the outcome of our clinical trials and validation studies and that such outcomes will support commercialization, the expected market penetration and size of the market for our products under development, including without limitation, Rolapitant™, Rayaldee™ (CTAP-101), hGH-CTP™, the 4Kscore, Factor VIIa-CTP, oxyntomodulin, and our point-of-care diagnostic products for Total-PSA, testosterone, and Vitamin D, the potential benefits of our products under development, including whether the 4Kscore will improve selection of candidates for prostate biopsy, predict the risk of distant metastases, and result in \$2 to 4 billion in healthcare savings, expected per patient savings, whether MOD-6031 will provide superior long-term therapy for obesity and Type II diabetes patients, our ability to successfully commercialize our product candidates such as Rolapitant, the 4Kscore, Rayaldee (CTAP-101), hGH-CTP, Factor VIIa-CTP, and oxyntomodulin, as well as products for other markets such as urology, women's health, cardiology, oncology, iPTH, and infectious disease, whether we will be able to develop Rayaldee (CTAP-101) for additional indications and whether Rayaldee (CTAP-101) will take significant market share in Stage 3 and 4 CKD patients with SHPT, whether Rayaldee (CTAP-101) will raise serum total 25-hydroxyvitamin D (25D) more effectively than any over-the-counter (OTC) or prescription (Rx) product currently marketed without the risk of hypercalcemia, whether we can reach more than half of the CKD population with a small sales force, our ability to establish a sales and marketing and clinical support infrastructure for Rayaldee and the timeline for doing so, the expected acceptance date of our Rayaldee NDA and PDUFA date, expectations regarding patent coverage, the expected timing for commencing, completing and obtaining results for our clinical trials and publication date for NCCN guidelines, the timing for release of trial data and seeking and obtaining FDA and European regulatory approvals as well as reimbursement coverage, and the timing of commercial launch of our product candidates, as well as other non-historical statements. These forward-looking statements are only predictions and reflect our views as of the date they were made, and we undertake no obligation to update such statements. Such statements are subject to many risks and uncertainties that could cause our activities or actual results to differ materially from the activities and results anticipated in forward-looking statements, including risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, the success of our collaboration with Pfizer, general market factors, competitive product development, product availability, federal and state regulations and legislation, and integration issues arising from the transactions, delays associated with development of novel technologies, unexpected difficulties and delays in validating and testing product candidates, the regulatory process for new products and indications, manufacturing issues that may arise, the cost of funding lengthy research programs, the need for and availability of additional capital, the possibility of infringing a third party's patents or other intellectual property rights, the uncertainty of obtaining patents covering our products and processes and in successfully enforcing them against third parties, and the possibility of litigation, among other factors, including all of the risks identified under the heading Risk Factors in our Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.



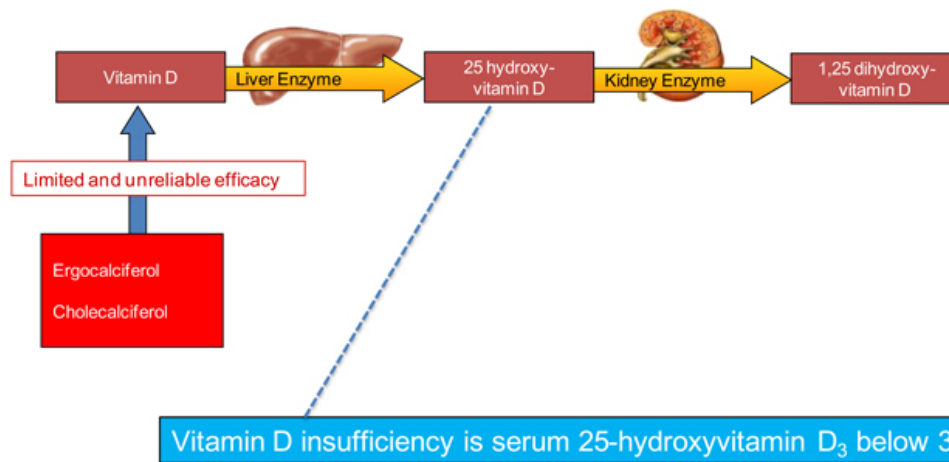
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## Rayaldee – Initial Indication Requested in New Drug Application

“Prevention and treatment of secondary  
hyperparathyroidism (SHPT)  
in patients with stage 3 or 4 chronic kidney disease  
(CKD)  
and vitamin D insufficiency”

Significance: First drug to target this important indication

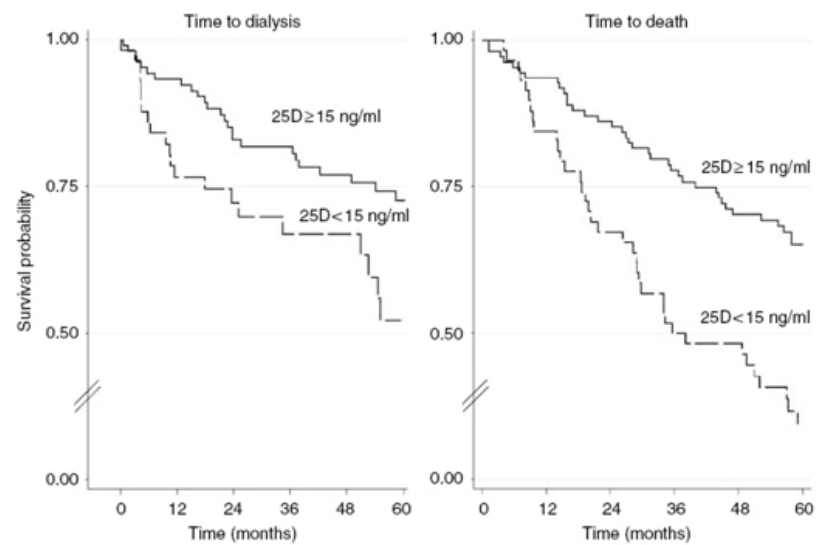
## What is Vitamin D Insufficiency?



## Diseases Associated with Vitamin D Insufficiency



## Vitamin D Insufficiency: Increases Mortality in CKD



## Market Opportunity: Chronic Kidney Disease (US)



















The CKD patient population is large and growing as a result of:

- Obesity
- Hypertension
- Diabetes

| Stage | Kidney Function     | CKD Prevalence | % of CKD Patients with          |              |                                  |
|-------|---------------------|----------------|---------------------------------|--------------|----------------------------------|
|       |                     |                | Vitamin D Insufficiency (↓ 25D) | SHPT (↑ PTH) | Hyperphosphatemia (↑ Phosphorus) |
| 3     | Moderate impairment | 18.7 Million*  | 71%                             | 40%          | 37%                              |
| 4     | Severe impairment   | 1.4 Million*   | 83%                             | 82%          | 50%                              |
| 5     | Failure             | 0.5 Million*   | 97%                             | 95%          | 70%                              |

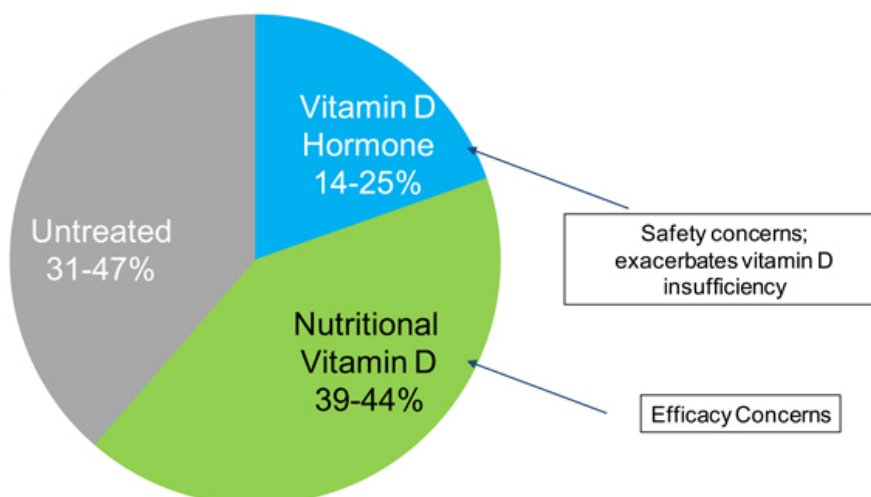
\*US Renal Data Service 2013 Annual Data Report  
Sources: Levin, A et al., Kidney International 2007; 71: pp.31-38; Gonzalez, E et al. Am J Nephrol 2004;24:503-510; LaClair, R et al. Am J Kidney Dis 2005;45:1026-1033; Tentori, F et al., Clin J Am Soc Nephrol 2015; 10:98-109

## Comparison of Vitamin D Therapies for Stage 3-4 CKD

| Drug        | Active  | Type | Effect on Blood Levels of:  |   |   |
|-------------|---|------|---|---|---|
|             |   |      | 25D**   | Ca  | iPTH  |
| Rayaldee    | Calcifediol<br>(25-hydroxyvitamin D <sub>3</sub> )                                  | Rx   |  |  |  |
| Vitamin D   | Cholecalciferol/Ergocalciferol<br>(vitamin D <sub>3</sub> /vitamin D <sub>2</sub> ) | OTC  |  |  |  |
| Drisdol™*   | Ergocalciferol<br>(vitamin D <sub>2</sub> )   | Rx   |  |  |  |
| Rocaltrol™* | Calcitriol<br>(1α,25-dihydroxyvitamin D <sub>3</sub> )                              | Rx   |  |  |  |
| Hectorol™*  | Doxercalciferol<br>(1α-hydroxyvitamin D <sub>2</sub> )                              | Rx   |  |  |  |
| Zemplar™*   | Paricalcitol<br>(19-nor-1α,25-dihydroxyvitamin D <sub>2</sub> )                     | Rx   |  |  |  |

## Rayaldee - Commercial Opportunity

Stage 3 & 4 CKD Treatment for  
SHPT

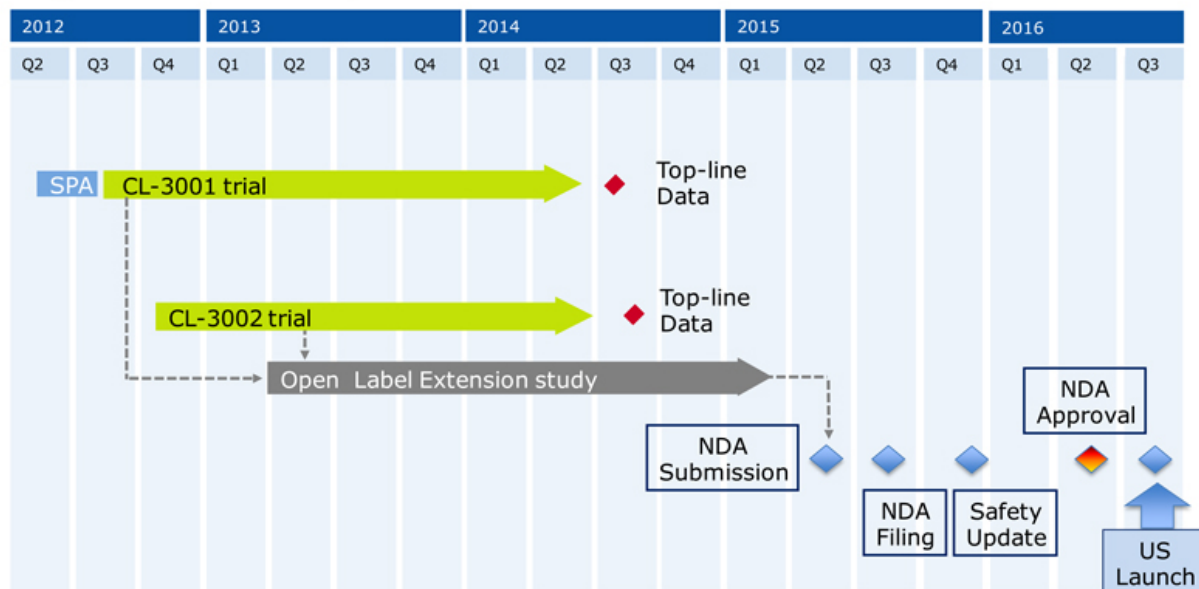


Rayaldee is expected to take significant market share in Stage 3 and 4 CKD patients suffering from SHPT – a potential \$12 billion revenue opportunity

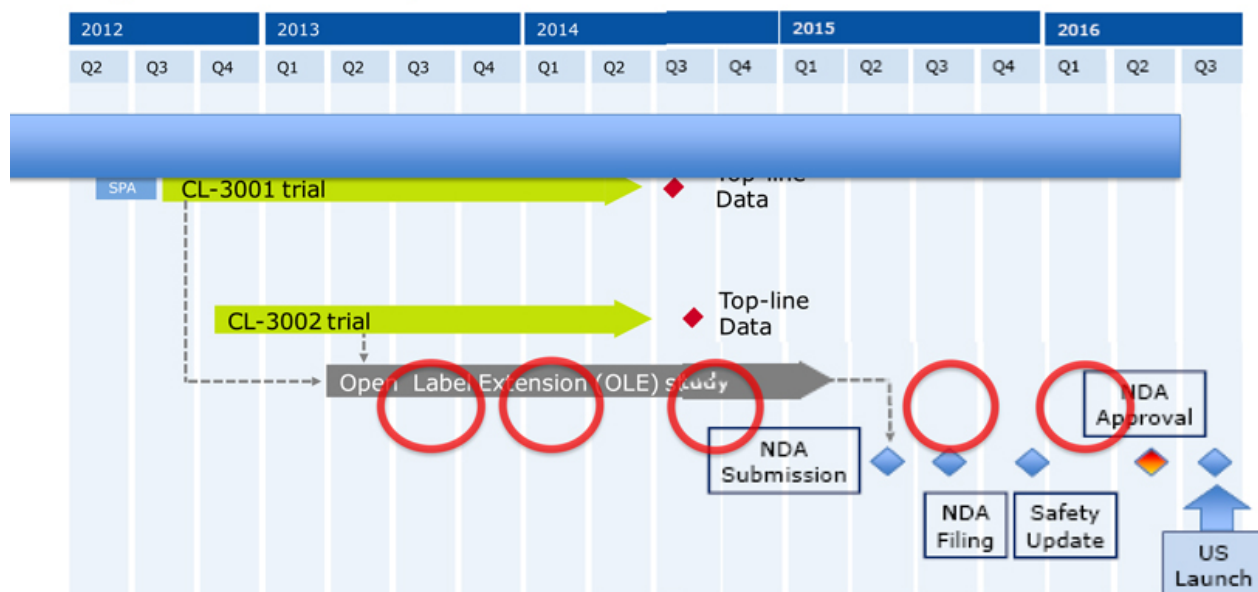
**OPKO HEALTH**  
Renal Division

Source: BioTrends Research Group, Inc. December 2013

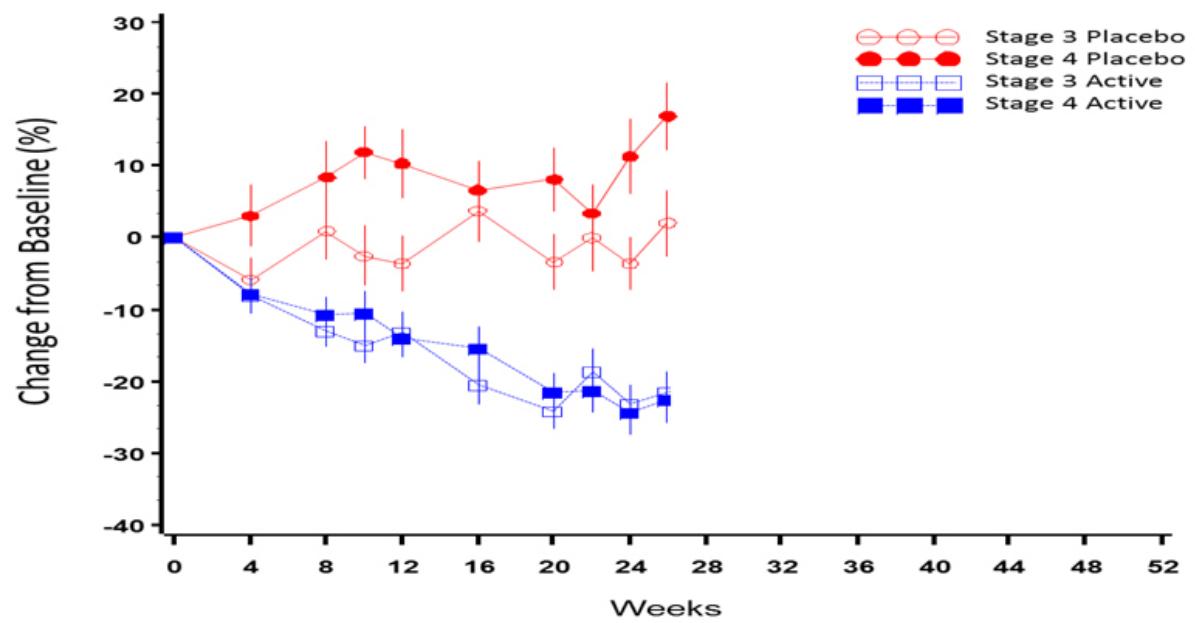
## Royaldee: Phase 3, NDA and US Launch Timelines



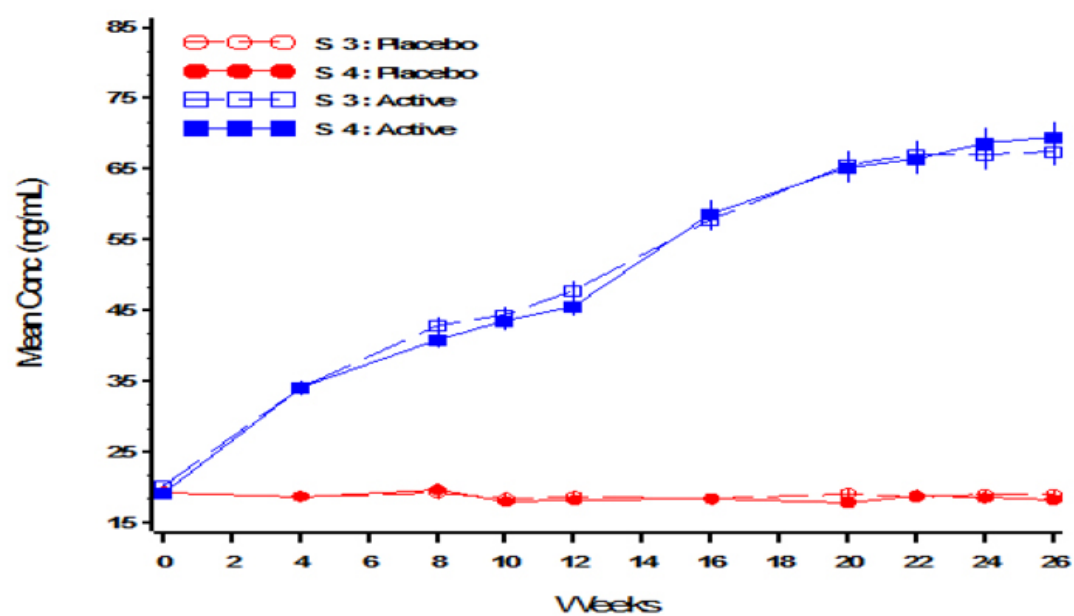
## Royaldee: Phase 3, NDA and US Launch Timelines



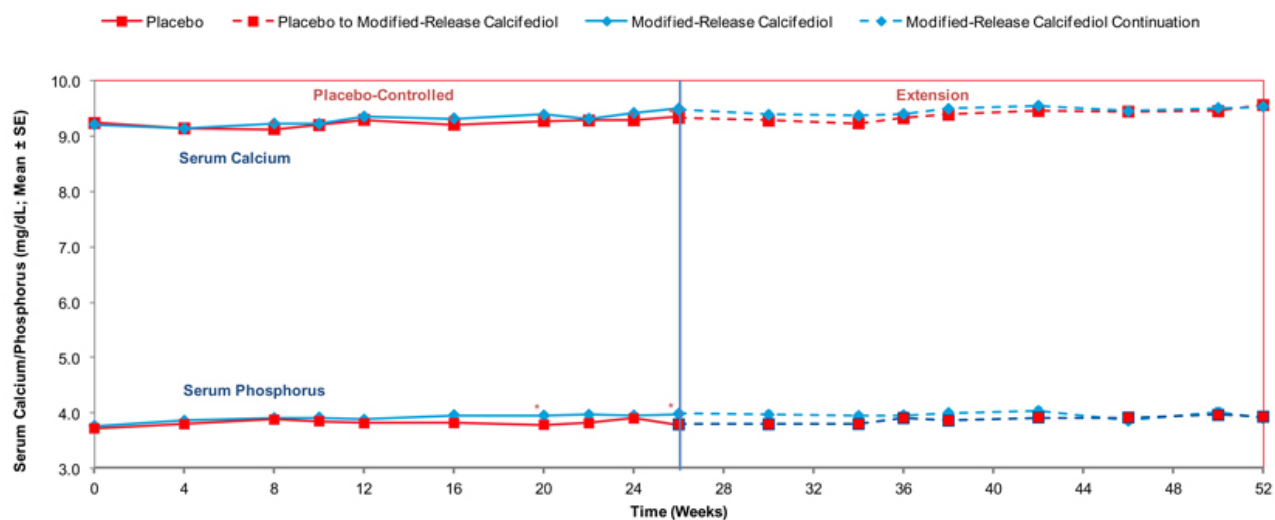
## Royaldee Top-Line Phase 3 Data: Plasma iPTH



## Rayaldee Top-Line Phase 3 Data: Serum 25D



## Royaldee Top-Line Phase 3 Data: Serum Ca & P



**OPKO HEALTH**  
Renal Division











\*Significantly different from placebo,  $p < 0.05$

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## Rayaldee – Key Steps to Commercialization

- NDA filing (accepted for full FDA review) in late July
- Marketing & sales management team to be hired in late 2015
- Sales representatives and clinical support specialists to be hired pre-launch
- PDUFA date: late May 2016
- Launch expected within 3 months of PDUFA date
- Initial line extension plans:
  - Additional phase 3 clinical trial(s) planned in stage 5 CKD
  - Phase 1 clinical trial ongoing for new oncology indication
  - Other indications being evaluated

## OPKO Pharmaceuticals–Advanced, Deep Pipeline

| Product                  | Indication                                      | Preclinical  | Phase 1 | Phase 2 | Phase 3 | Milestone                                     | Market Size |
|--------------------------|---|--|---------|---------|---------|---|-------------|
| Royaldee™<br>(CTAP101)   | SHPT<br>(CKD Stage 3-4 Patients)                |  |         |         |         | NDA submitted<br>May 2015                     | \$12.0 BN   |
| hGH-CTP                  | hGH deficiency                                  |  |         |         |         |   | \$3.0 BN    |
| Alpharen™<br>(Fermagate) | Hyperphosphatemia<br>(CKD Stage 5 Patients)     |  |         |         |         |   | \$1.2 BN    |
| Rolapitant               | CINV  |  |         |         |         | PDUFA date<br>September 5,<br>2015            | \$1.5 BN    |
| Sci-B-Vac™               | Hepatitis B<br>(CKD Stage 5 Patients)           |  |         |         |         |   | \$0.2BN     |
| CTAP201                  | Mild to moderate SHPT<br>(CKD Stage 5 Patients) |   |         |         |         |   | \$1.1 BN    |
| Factor VIIa-CTP          | Hemophilia                                      |   |         |         |         | Phase 2a trial<br>will commence<br>in 3Q 2015 | \$1.7 BN    |
| Oxyntomodulin            | Diabetes, Obesity                               |   |         |         |         | Phase I trial<br>targeted for<br>2H 2015      | \$15 BN     |
| AntagoNAT<br>Platform    | Cancer, CV, metabolic and<br>orphan disease     |   |         |         |         |   | \$1.0 BN    |
| CYP24 Inhibitors         | SHPT, CKD, cancer                               |   |         |         |         | Phase 1 trial<br>targeted for<br>4Q 2016      | \$1.0 BN    |








**Thanks!**

***OPKO***

**June 2015**

## BioReference Laboratories Snapshot

| Division  | Key Products   | Markets   |
|---|--|---|
|  | Automated, high volume IVD,<br>Health Informatics,<br>HIV, HCV, other Molecular Dx | Physician Offices,<br>Health Facilities,<br>Correctional Facilities                           |
|  | Flow Cytometry,<br>IHC, FISH, ISH, Microarray,<br>Morphology                       | Hematologists,<br>Oncologists,<br>Hospital Pathologists                                       |
|  | Image-Directed Cytology (PAP)<br>HPV, STI  | Obstetricians,<br>Gynecologists,<br>Maternal-Fetal Medicine                                   |
|  | NextGen & Sanger Sequencing,<br>Array Comparative Genomic<br>Hybridization (aCGH)  | Geneticists, Medical Centers,<br>Children's Hospitals,<br>Physicians managing genetic disease |
|  | Automated, high volume IVD,<br>Health Informatics,<br>HIV, HCV, other Molecular Dx | Physicians' offices in Spanish-<br>Speaking Communities                                       |

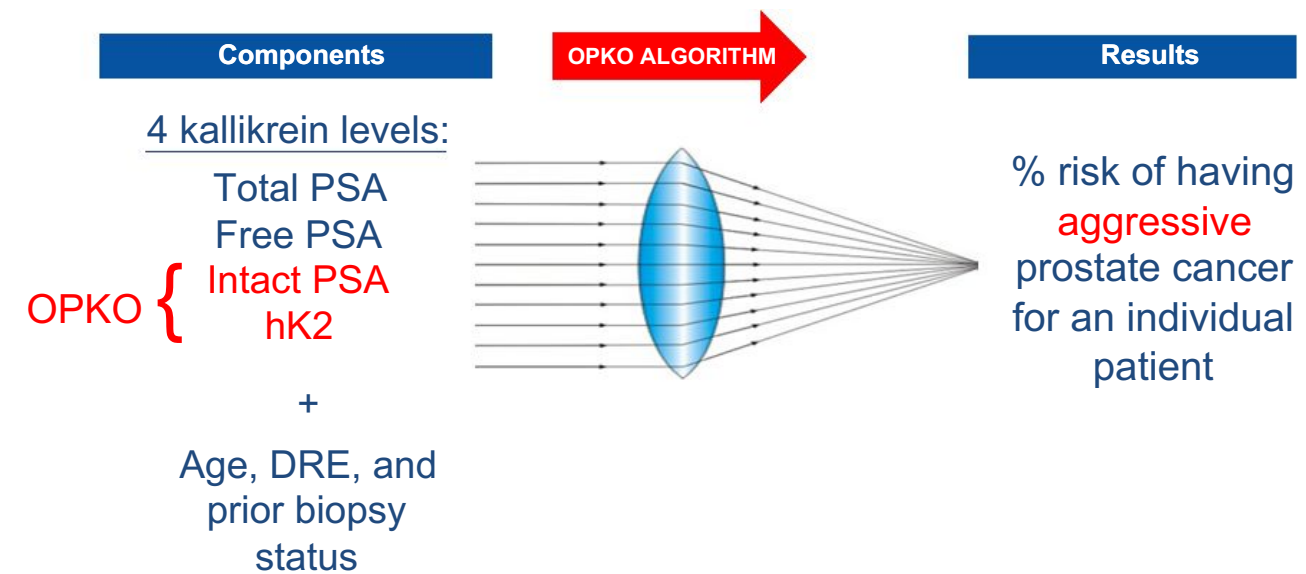
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# **BioReference Laboratories + OPKO Health = Strong Customer and Product Benefits**

- **BioReference Laboratories**
  - The 3<sup>rd</sup> largest clinical laboratory in the US (after Quest and LabCorp) with scale to reach large markets in the Northeastern US, Florida, California, and Texas
  - Fast growing, innovative molecular diagnostics business with expertise in technologies enabling meaningful molecular medicine (NextGen sequencing, aCGH)
  - Full service routine testing menu for primary care physicians and specialists
  - High value testing capabilities serving key specialties (Women's Health, Oncology) and other clinicians managing genetic disease
  - Team of about 400 sales, customer service and marketing personnel
  - Patient Service Centers with blood draw capability at over 170 locations
- **OPKO Health**
  - Specialists in Uro pathology, including anatomic pathology, IHC, cytology and FISH, serving the diagnostic testing needs of urologists
  - The 4Kscore Test for aggressive prostate cancer
  - Claros 1 for in-office immunoassay results in 10 minutes from a fingerstick blood sample
- **Combined Strengths**
  - Nation wide insurance contract coverage and large payer relationships
  - Access to the Primary Care Physician market for 4Kscore and Claros platform
  - Access to over 170 BRL patient service centers for 4Kscore blood draw
  - Blood specimen transportation network and high volume testing operation
  - Addition of urology to BRL specialty diagnostic services capability

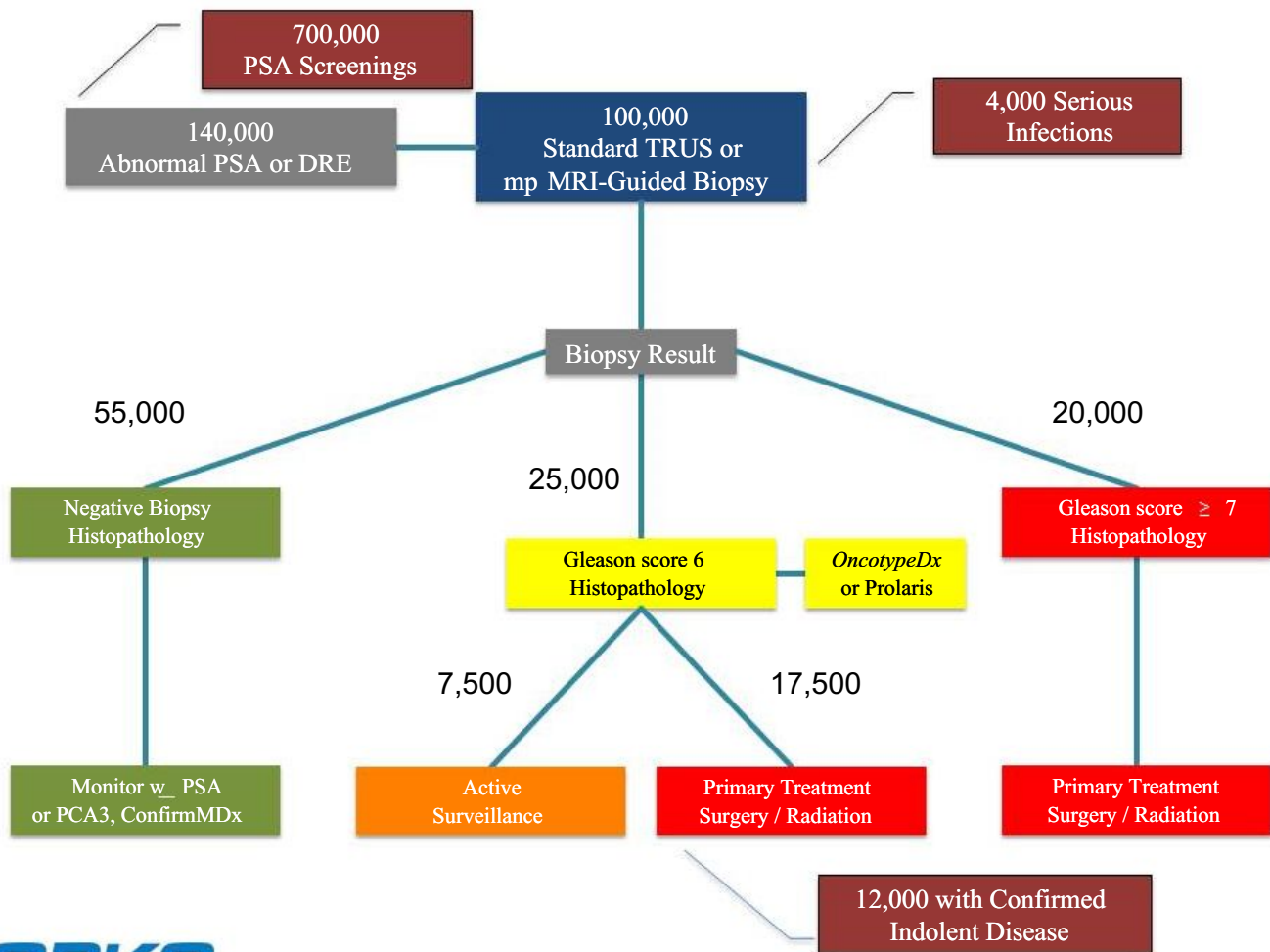


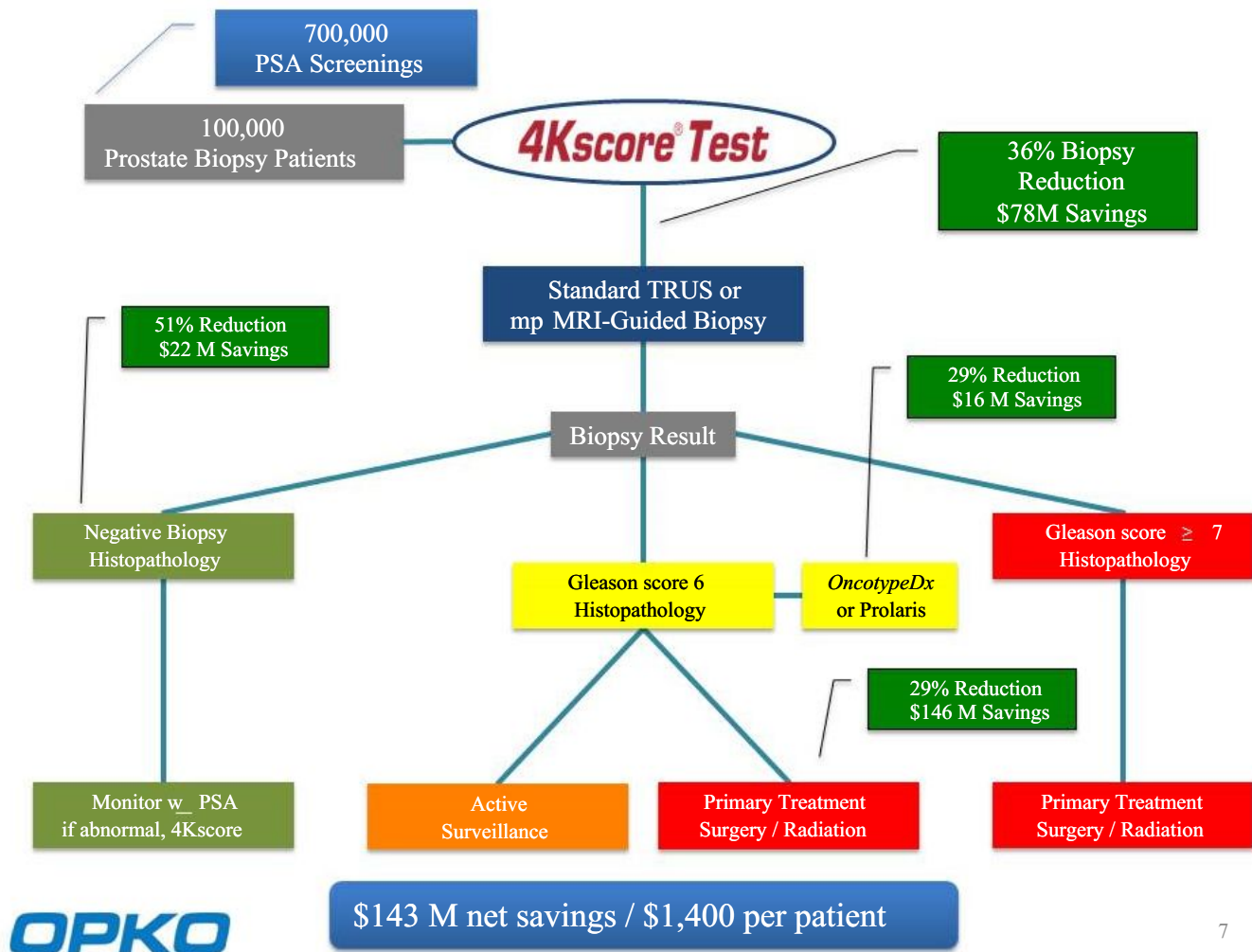
# What is the 4Kscore Test?



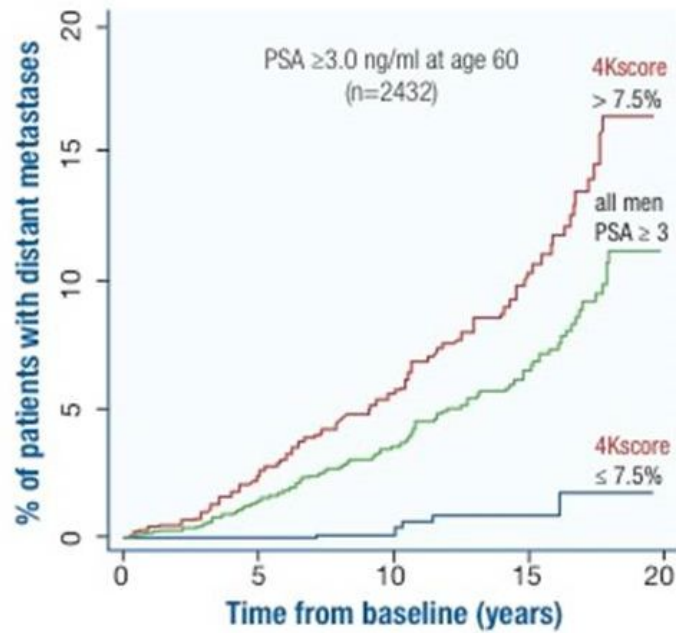
**OPKO**







# The 4Kscore Test Predicts Metastases Within 20 years <sup>1</sup>



16%

< 2%

**OPKO**

<sup>1</sup> Improving the Specificity of Screening for Lethal Prostate Cancer Using Prostate-specific Antigen and a Panel of Kallikrein Markers: A Nested Case-Control Study  
European Urology (in press)

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## 4Kscore Commercial Update

- 4Kscore ProtecT study published – over 6,000 subjects
- Total dossier for the 4Kscore Test now includes clinical data on over 22,000 subjects in 12 peer reviewed publications
- Over 900 US urologists have used the 4Kscore test in routine practice
- American Urological Society Meeting in New Orleans May, 2015 – six podium or poster presentations
- Next milestones:
  - NCCN Early Detection Guidelines 3Q2015
  - CPT Code active July 1, 2015 – billing Medicare and Private Insurance
  - Medicare and private insurance coverage for test: 2015/16



## Claros<sup>®</sup> 1: Rapid Testing in the Physician Office

**1-2**  
mins

10 mins



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## Claros 1 Platform Addresses Large Testing Markets Commercial Leverage with Bio-Reference Sales Team

- Testosterone
  - US test volume: 15 million tests, \$525 M
  - 510(k) filing in 1H2016
- PSA
  - US test volume: 30 million tests, \$750 M
  - Intended use to focus on detection claim
  - Modular PMA filing in 1H2106
- Renal panel in Development
  - Vitamin D
    - US test volume: 70 million tests, \$3.5 B
  - iPTH
  - Cystatin C
- Lyme Disease
  - Claros 1 selected as platform for an NIH funded diagnostic development
  - OPKO has all rights to diagnostic test (\$120M US Market)





18 June 2015

## General Overview



# Our Vision

*We are a leading specialty pharmaceutical company*

To be the leading  
developer and supplier  
of highly potent  
pharmaceutical  
products for global  
markets



*Click above to view  
EirGen's expanded facility*

**OPKO**



# Ireland: Fact Sheet



- Population 4.2 million
- Largest Exporter of Pharmaceuticals in the World, 8<sup>th</sup> largest producer. 9 of World's Top 10 Pharma Companies Located in Ireland
- Home to 120 Pharma companies; 33 pharma and biopharma plants are FDA approved. 25,000 direct & 25,000 indirect employees serviced by excellent university programs
- English speaking and excellent compliance track record
- Waterford is situated in the South East of Ireland. Population of 50,000 people.

# Business Overview

## A Specialty Pharmaceutical Company

Focused on the development and commercial supply of highly potent pharmaceutical products

**In a purpose built, state of the art,  
high containment facility**



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**GENGEN  
PHARMA**

# Introductions – EirGen Founders

## PATSY CARNEY

**Chief Executive Officer/ Co-Founder**

- » Co-founded EirGen
- » Previously Head of Operations and BD for IVAX Ireland (14 years)
- » Holds a BSc In Industrial Chemistry from University of Limerick and an MBA from University of Limerick

## TOM BRENNAN

**Chief Technical Officer/ Co-Founder**

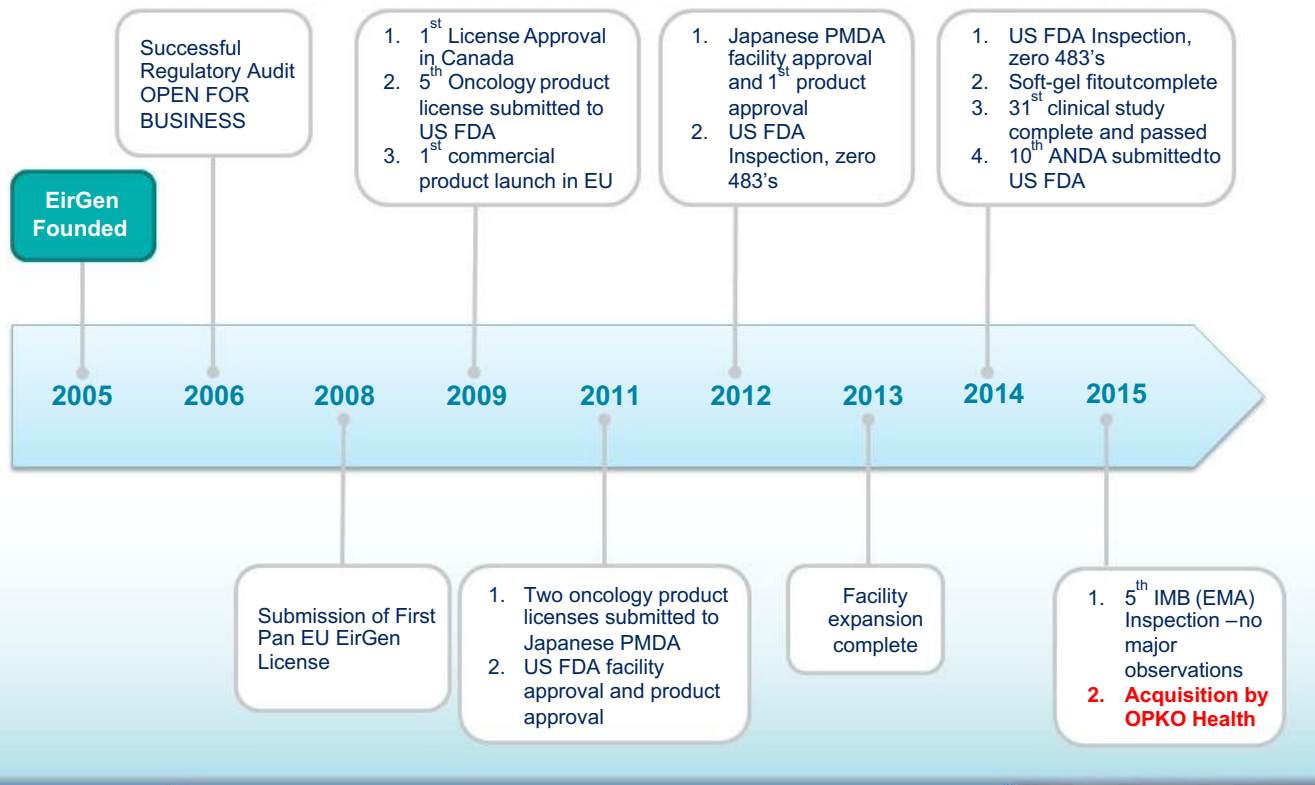
- » Co-Founded EirGen
- » Previously held senior technical positions with IVAX and Stada
- » 10 Years IVAX Ireland as R&D Manager
- » Holds a BSc in Chemistry from Cork IT, an MSc in Industrial Pharmacy from University of Manchester and an MBA from University of Limerick
- » Qualified Person, Six Sigma Black Belt, Packaging Technologist



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# EirGen Key Milestones



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# Current Position: where we are now

- » 98 employees, all graduates
- » 31 successful Clinical Studies
- » 42 countries for commercial product supply
- » 27 products in R&D
- » 10 Products filed with US FDA to date, 3 approved
- » 4 Pan EU CTD Dossiers filed to date and approved
- » 5 Oncology Products filed with Japanese PMDA; 4 approved



# Current Position: Regulatory Status

- » Global license submission strategy
- » FDA, Aug 2014, no 483's
- » IMB (EMA), May 2015, no major observations
- » Licensed to handle Cytotoxic Materials



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# Therapeutic Focus

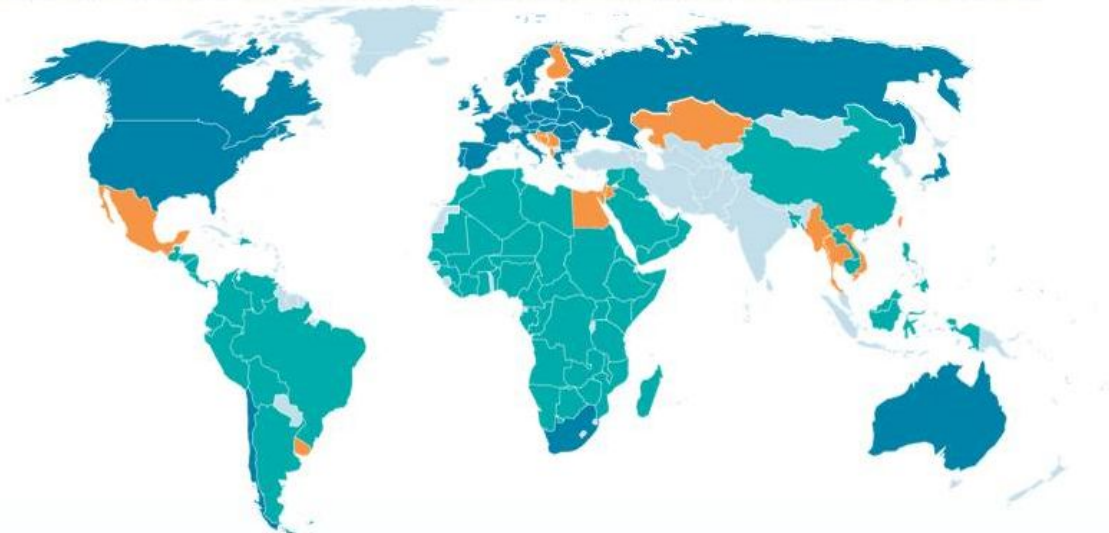
- » Oncology Molecules
- » Immunosuppressants
- » Prostaglandins
- » Cytotoxic Molecules
- » Hormonals
- » Steroids



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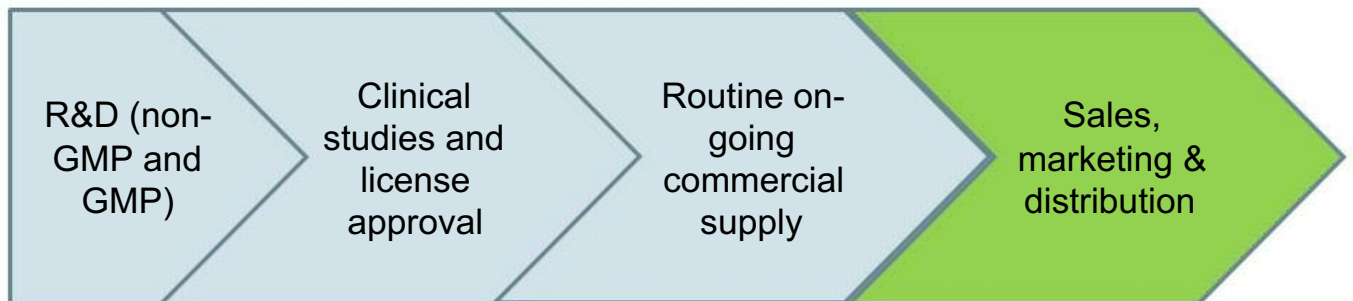
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# Global Presence



| Category                 | Countries |
|--------------------------|-----------|
| Commercial(BLUE)         | 42        |
| LicensesPending(ORANGE)  | 20        |
| CustomerContracts(GREEN) | 85        |

# EirGen Existing Business Model



Strategic Partner

**OPKO**



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# EirGen OPKO Opportunities

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- » **API Vertical Integration** - Synergies with OPKO Finetech, Israel
- » **Product Development & Manufacturing** - OPKO's current & future products
- » **Irish based Supply Chain Hub** - global distribution of OPKO Products
- » **Tax efficient R&D Hub** - proven R&D track record since incorporation





Thank You



[www.EirGen.com](http://www.EirGen.com)